



**PATENT** 

Attorney Docket No.: 18184-0018-01-US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Patent Application of

: Group Art Unit: Not Yet Assigned

Steven M. Leventer, et.al.

Serial No:

10/578,522

: Examiner: Not Yet Assigned

Filed:

May 8, 2006

For:

TREATMENT OF INFLAMMATORY

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## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, submitted herewith are copies of the references listed in the accompanying form PTO-1449, except for any U.S. patents and published U.S. patent applications which may be listed.

The Examiner is respectfully requested to review the items listed on the PTO Form 1449 and make them of record in the instant application as required by M.P.E.P. §609. It is requested that the Examiner initial the enclosed duplicate substitute Form 1449, and return one copy to the undersigned.

## **CERTIFICATE OF MAILING** UNDER 37 C.F.R. 1.8(a)

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Appl. No. 10/578,522 Information Disclosure Statement

This Information Disclosure Statement should not be construed as a representation that the cited references are material or prior art, or that more relevant references do not exist.

This statement is being submitted before receipt of any office action on the merits. Thus, no fee is due for the filing of this paper. However, if a fee is due, please charge deposit account 50-0573.

Respectfully submitted,

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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U.S. PATENT DOCU	MENTS
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13 NF 8 T			U.S. PA	TENT DOCUMENTS			· · · · · · · · · · · · · · · · · · ·
EXAMINER NITIAL	ARRES	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	AA	3,736,315	05/29/1973	Korosi et al.	260	239	
	AB	Re. 30,014	05/29/1979	Körosi, et al.	260	239	
	AC	4,322,346	03/30/1982	Kórósi, et al.	260	239	
	AD	4,423,044	12/27/1983	Kórösi, et al.	424	244	
	AE	4,614,740	09/30/1986	Láng, et al.	514	221	·
	AF	4,835,152	05/30/1989	Korösi, et al.	514	220	
	AG	4,840,948	06/20/1989	Láng, et al.	514	221	
	AH	5,204,343	04/20/1993	Andrási, et al.	514	221	
	AI	5,288,863	02/22/1994	Somogyi, et al.	540	567	
	AJ	5,459,137	10/17/1995	Andrási, et al.	514	220	
	AK	5,519,019	05/21/1996	Andrási, et al.	514	220	
	AL	5,521,174	05/28/1996	Andrási, et al.	514	220	
	AM	5,639,751	06/17/1997	Andrási, et al.	514	220	
	AN	5,891,871	04/06/1999	Xia, et al.	514	219	
	AO	6,075,018	06/13/2000	Vágó, et al.	514	221	
	AP	6,080,736	06/27/2000	Landry, et al.	514	221	
	AQ	6,638,928	10/28/2003	Harris et al.	514	221	
	AR	6,649,607	11/18/2003	Leventer, et al.	514	221	
	AS	6,683,072	01/27/2004	Kucharik, et al.	514	211.13	
	AT	6,864,251	03/08/2005	Kucharik, et al.	514	221	
	AU	7,022,700	04/04/2006	Harris, et al.	514	221	
	AV	2004/0138209	07/15/2004	Kucharik, et al.	514	221	
	AW	2004/0138210	07/15/2004	Harris, et al.	514	221	
	AX	2004/0152695	08/05/2004	Harris, et al.	514	221	
,	AY	2004/0157833	08/12/2004	Harris, et al.	514	221	
	AZ	2004/0162284	08/19/2004	Harris, et al.	514	221	
	BA	2004/0224943	11/11/2004	Leventer, et al.	514	221	
	BB	2004/0229867	11/18/2004	Kucharik	514	221	
	BC	2005/0075329	04/07/2005	Leventer, et al.	514	221	
	BD	2005/0288277	12/29/2005	Kucharik, et al.	514	221	

FOREIGN PATENT DOCUMENTS

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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	BE	EP 0 492 485	12/31/91	Europe		C07D	491/04	YES	NO
	BF	178516	3/31/83	Hungary		C07D	243/00	x	<del>-    </del>
	BG	178519	3/31/83	Hungary		C07D	24300	x	
	BH	WO 92/11262	7/9/92	WIPO		C07D	491/056		
<del>.</del>	BI	WO 00/24400	5/4/00	WIPO		A61K	31/551		1
		OTHER DOC	CUMENTS (Inc	luding Author,	Title, Date, Pe	rtinent Pages,	Etc.)	<u> </u>	
. <del></del>	BJ	Y. Adachi et al., "U Yakugaku, 1987, 18	Jse of tofisopan	n (Grandaxin®)	in autonomic i			syndrome", I	gaku to
	BK	T. Aoyagi <i>et al.</i> , Yagastrointestinal con	akuri to Chiryo, nplaints", 1992,	"Clinical evaluation 20(2), 295-305	ation of tofisor , Japan. (Trans	lation provide	d.)		
-	BL	S. Asano et al., "St gastrointestinal con	ditions", Shinya	aku to Rinsho, 1	993, <i>42</i> (12), 9:	5-100, Japan. (	Translation pro	ovided.)	
	BM	V.S. Chadwick, et a 2002, 122(7), 1778	-83.	•					
	BN	S.M. Collins, et al.	"The putative	role of inflamma	ation in the irri	table bowel sy	ndrome", Gut,	2001, <i>49</i> (6), 7	743-45.
	ВО	M. Csillag et al., "164-69.	The treatment of	f climacteric syn	drome with to	fizopam (gran	daxin)", <i>Ther F</i>	Hung, 1975, 2.	3(4),
	BP	E. Fogassy, et al., 'ethyl-7,8-dimethox Heterocycles Synth	y-5H-2,3-Benzo	odiazepine (Tofi	sopam). " in F	I.C. Van der P	las, et al. (Eds.)	) "Bio-Organi	
	BQ	F. Galdiero, <i>et al.</i> , 57. No. 26, pp. 241	"Effects of Benz 3-2423, 1995	zodiazepines on	Immunodefici	ency and Resi	stance in Mice'		s, Vol.
	BR	F. Gatta, et al., "De						GI	
	BS	H. Hanajima, "Effe 15(5), 307-17, Japa	n. (Translation	provided.)					
	BT	E. Horvath, et al.,		benzodiazepine	s, their specific	binding to the	e basal ganglia'	", Progress in	
	BU	Neurobiology, 200 S. Kalashnikov, et	al., "Immunomo	odulating effects	of tofizopam	(Grandaxin®)	and diazepam	in vitro" Med	iators of
	BV	A. Kato et al., "Cli		randavin for un	rique unidenti	fied complaints	" Yakuri to C	hinya 1987 1	5(8)
	D V	163-71, Japan. (Tra			rious uniucilli	nou complaind	, ranurrio Ci	, yo, 1701, 1	~(0),

J. Kanto, et al., "Tofizopam: a benzodiazepine derivative without sedative effect", *International Journal of Clinical Pharmacology, Therapy and Toxicology*, 1982, 20(7), 309-12.

DATE CONSIDERED **EXAMINER** 

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		OTHER DOC	UMENTS (Incli	uding Author,	Title, Date, Pertin	ent Pages,	Etc.)	
	BX	S. Kishimoto <i>et al.</i> , Japan. (Translation	"Clinical effect					<b>19</b> , <i>17</i> (5): 457-64,
	BY	A. Kitano et al., "Cl Rinsho, 1988, 37(9)				e gastrointe	stinal complain	nts", Shinyaku to
	BZ	M. Kojima, et al., "194. (Translation pro	Effects of Tofiso	pam on Lower	Digestive Tract l	Dysfunction	ı", Clinical Rep	port, 1996, 30(5), 989-
	CA	Y. Matsuo, et al., "E (Translation provide	ed.)					
	СВ	M. Osipenko et al., Terapevt. Arkhiv, 20				l diseases o	f the gastrointe	estinal tract.",
	CC	O. Oyesanmi, et al.,				sychosoma	tics, 199, 40(5)	), 414-21.
	CD	A. Pakkanen et al., Premedication", Br.	J. Anaesth., 198	30, <i>52</i> , 1009-12	2.			
	CF	I Petocz et al "T	he Main Pharma	cological Char	acteristics of Gran	ndaxin (Tot	isonam EGYT	[-341]". Therania

J. Szegó et al., "Selected passages from the clinical-pharmacological and clinical trials of grandaxin", Acta Pharm. CI Hung., 1993, 63, 91-98, Hungary. (Translation provided.) CJ H. Takada et al., "Clinical study of grandaxin for unidentified complaints", Yakuri to Chiryo, 1989, 17(3), 381-92, Japan. (Translation provided.) 1. Tarnawa, et al., "Structure-Activity Relationships of 2,3-Benzodiazepine Compounds With Glutamate CK Antagonistic Action", Bioorg. & Med. Chem. Lett., 1993, 3(1), 99-104. E. Tomori, et al., "Investigation of Metabolites of Tofizopam in Man and Animals", Pol J. Pharmacol. Pharm., CL 1984, 38, 423-30.

E. Tomori, et al., "Investigation of the Metabolites of Tofizopam in Man and Animals by Gas-Liquid Chromatography-Mass Spectrometry", Journal of Chromatography, 1982, 241, 89-99.

J. Visy, et al., "The Role of Configuration and Conformation in the Binding of 2,3-Benzodiazepines to Human Serum Albumin", Chirality, 1989, 1, 271-75. K. Yamaguchi et al., "Tofisopam, a new 2,3-benzodiazepine. Inhibition of changes induced by stress loading and

L. Petócz, "A tofizopam (Grandaxin®) farmakológiai hatásai", Acta Pharm. Hung.. 1993, 63, 79-82. (Translation

J. Ristelhueber, "Utility of a new anxiolytic, tofisopam, in current gastroenterology practice", Revue Française de

M. Rizzo, "Chromatographic separation of 2,3-benzodiazepines", Journal of Chromatography B, 2000, 747, 203-16.

hypothalamic stimulation", Can. J. Physiol. Pharmacol., 1983, 16, 619-25.

Gastro-Enterologie, 1977, 125, 49-52, France. (Translation provided.)

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**DATE CONSIDERED** 

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Hungarica, 1975, 23(4), 134-138.

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	CP	K. Yoshikawa et al. 195-202, Japan. (Tr				i) on several		, Hiju, 1993, 33(1),
		173-202, Japan. (11	ansiation prov	idea.)		<del></del>		
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